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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/868,744 | SCHEPERS ET AL. | |
| | Examiner | Art Unit | |
| | Ashwin Mehta | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7312002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objections*

1. Claims 3-5, 10, 13, and 16 are objected to for the following reasons:

Claim 3 is objected to for failing to comply with the sequence rules of 37 CFR 1.821-1.825. The claim refers to the sequence shown in Figure 3. The claim must identify that sequence with its sequence identifier.

Claims 4 and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. Parent claim 1 indicates that the method comprises a heterologous DNA construct including a DNA sequence adapted to express RNA. Claims 4 and 10 attempt limit the RNA to code for a heterologous protein. However, the RNA expressed by the DNA sequence in claim 1 is heterologous, as claim 1 indicates that the DNA construct is heterologous.

Claims 5 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. Claims 5 and 13 indicate that RNA encodes for a homologous protein. However, claim 1 and claim 9 indicate that the DNA construct is heterologous. Claim 5 and 13 therefore broaden the scope of the claims from which they depend.

The objections to claims 4, 5, 10, and 13 are made assuming (see the rejection under 35 U.S.C. 112, 2$^{nd}$ paragraph below) that "heterologous" refers to genes and gene products not

found in the host cell, and "homologous" refers to genes and gene products that are endogenous to the host cell. Removing the term, "heterologous" from the recitation, "heterologous DNA construct" in claims 1 and 9 will overcome the objections to claims 4, 5, 10, and 13.

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. Claim 16 is directed to a vector, and depends from claim 1. However, claim 1 is directed to a method. As claim 16 is not directed to a method or a product produced by the method of claim 1, it does not further limit the method of claim 1.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 3-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the modified gene" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Further in claim 1: the recitation, "a reduced tendency to silencing" renders the claim indefinite. It is not clear what is meant by this recitation. It is also not clear what is meant by "tendency," in the context of the claim. The metes and bounds of the claim are unclear.

In claims 1, 9, 10, 12-14, 16, 20, and 21: the term, "adapted" renders the claims indefinite. It is not exactly clear what the meaning of this term is in the context of the claims, making the metes and bounds of the claims unclear.

In claims 1, 4-7, 9-11, 13-15, and 21: the terms "heterologous" or "homologous" render the claims indefinite. A discussion on page 4 about the types of genes that can be expressed in the claimed invention includes the terms, "heterologous gene" and " homologous gene" (lines 4-22). However, the distinction between "heterologous" and "homologous" is not clear. The discussion on page 4 indicates that heterologous genes may be used to up- or down-regulate homologous genes, which could indicate that heterologous genes are not endogenous to the host plant, while homologous genes are. However, this is unclear since the specification does not provide definitions for these terms. Further, claims 1 and 9 mentions that the DNA constructs that are transformed into the host plant are heterologous DNA constructs, yet dependent claims 5 and 13 indicate that the heterologous DNA construct comprises DNA that expresses RNA that produces an homologous protein. The meanings of "heterologous" and "homologous" are not clear.

In claim 3: the recitation, "substantially" renders the claim indefinite. The meaning of the term in the context of the claim is not clear. It is not clear when a nucleotide sequence is no longer considered "substantially" the sequence shown in Figure 3.

In claim 7: the recitation, "a homologous protein" in lines 2-3 renders the claim indefinite. Because of the article "a," it is not clear if the homologous protein mentioned in claim 7 is the same as that mentioned in claim 6. It is suggested that the article "a" in line 2 of claim 7 be replaced with --said--.

In claim 9: the recitation, "may be produced" renders the claim indefinite. It is not clear how else the plant cells may be produced. The metes and bounds of the claim are unclear.

In claims 9-15: the claims are dependent to claim 1, and are drawn to genetically modified *Compositae* plant cells. However, claim 1 is drawn to a method that results in genetically modified *Compositae* plants, as opposed to plant cells. Claim 1 does not make any mention of genetically modified plant cells.

In claim 15: the claim indicates that the expressed RNA in the plant cell of claim 12 is antisense to a DNA coding a homologous protein. However, claim 12 indicates that the DNA construct expresses the oxox gene.

In claim 16: the recitation, "useful in the process of claim 1" in line 1 renders the claim indefinite. It is not clear how this recitation defines the claimed invention. For example, does it indicate that the vector cannot be used for any other purpose? It is suggested that the recitation be deleted.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 3-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any method of producing a genetically-modified *Compositae* plant in which the expression of the modified gene has a reduced tendency to silencing, comprising transforming the plant with a heterologous DNA construct including a DNA sequence adapted to express RNA under the control of the actin2 (ACT2) gene promoter; or said method wherein the promoter has substantially the sequence shown in Figure 3; or said method wherein the plant is lettuce or sunflower; or any genetically modified *Compositae* plant cell produced by said method; or said cell wherein the DNA construct expresses the oxox gene; or any vector comprising said DNA construct, wherein the DNA sequence comprises the gus gene or the oxox gene; or any *Compositae* plant comprising said cells, or wherein the plants are any lettuce or sunflower, or wherein said plant expresses oxox and is resistant to sclerotinia, or which expresses any heterologous gene conferring herbicide resistance.

The specification admits that the promoter of the actin2 gene of *Arabidopsis* is taught in the prior art (page 3). A binary vector comprising the *Arabidopsis* act2 promoter fused to the GUS coding sequence was used to stably transform lettuce plants via *Agrobacterium*. Lettuce plants were also transformed with a vector comprising the CaMV 35S promoter fused to the GUS coding sequence. The specification indicates that the act2/GUS transformants showed higher and more uniform levels of GUS activity versus the CaMV 35S/GUS transformants (page 6). Various tissues were taken from twelve different act2/GUS transformants and assayed for GUS activity levels. The specification indicates that tissues from 9 of the transformants showed consistent levels of activity, and a certain degree of variability in expression in tissues of three of

the transformants (paragraph bridging pages 6-7). Act2/GUS plants were also analyzed at the T1 generation. The specification indicates that there was no significant loss of GUS activity in the T1 generation. The specification indicates that there is a total inhibition of gene activity in 90% of the events during transmission from one generation to the next with the 35S/GUS construct (pages 7-9). The specification also indicates that the sequence of the act2 promoter shown in Figure 3 was modified to insert restriction sites near the transcription start site, and that the coding sequence of an oxalate oxidase (oxox) gene was inserted (pages 9-10). The specification indicates that good levels of oxox activity were observed in transient assays with lettuce and sunflower extracts (paragraph bridging pages 10-11).

A review of claim 1 indicates that the promoter of any actin2 gene is essential to the claimed invention, and is part of the starting material for the method. The claim does not limit the promoter to be from any particular gene of any particular organism. Claim 3 indicates that the promoter has substantially the sequence shown in Figure 3. However, since the term "substantially" is not defined in the specification, it is not clear what differentiates the ACT2 gene promoter of Figure 3 from any other promoter.

As discussed above, the specification indicates that the ACT2 gene promoter of *Arabidopsis* is taught in the prior art. However, the specification does not describe the nucleotide sequence of any other ACT2 gene. The specification does not describe the nucleotide sequences of the *Arabidopsis* ACT2 promoter that distinguishes it from other promoters. The specification indicates that actin2 promoters can be isolated from other sources (page 3). However, such promoters are not disclosed in the specification. ). Also see Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a

DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself".

The claims are also drawn to any and all Compositae plants and cells produced by the claimed method, wherein any DNA sequence encoding any product may be operably linked to the act2 promoter. However, the specification only describes genetically modified lettuce plants comprising the *Arabidopsis* act2 promoter fused to GUS. The structures and functions of different transgenic plants and cells encompassed by the claims would vary, depending on the function of the product encoded by the DNA sequence. The structures and functions of all such plant and cells encompassed by the claims are not described in the specification. Given the breadth of the claims encompassing actin2 promoters that were not known in the art at the time the invention was filed, and any and all genetically modified *Compositae* plants and cells produced by the claimed method, it is submitted that the specification fails to provide an adequate written description of the multitude of actin2 promoter sequences encompassed by the claims.

4. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method using the ACT2 promoter from Arabidopsis and shown in Figure 3, does not reasonably provide enablement for other ACT2 promoters, a reduced tendency to silencing of any gene, or all genetically-modified *Compositae* plants and cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any method of producing a genetically-modified *Compositae* plant in which the expression of the modified gene has a reduced tendency to silencing, comprising transforming the plant with a heterologous DNA construct including a DNA sequence adapted to express RNA under the control of the actin2 (ACT2) gene promoter; or said method wherein the promoter has substantially the sequence shown in Figure 3; or said method wherein the plant is lettuce or sunflower; or any genetically modified *Compositae* plant cell produced by said method; or said cell wherein the DNA construct expresses the oxox gene; or any vector comprising said DNA construct, wherein the DNA sequence comprises the gus gene or the oxox gene; or any *Compositae* plant comprising said cells, or wherein the plants are any lettuce or sunflower, or wherein said plant expresses oxox and is resistant to sclerotinia, or which expresses any heterologous gene conferring herbicide resistance.

As discussed above, the specification teaches the construction of a vector comprising the *Arabidopsis* actin2 gene promoter operably linked to the GUS coding sequence. The vector was introduced into lettuce plants via *Agrobacterium*. A sunflower explant was also transiently transformed with a vector comprising the oxox gene operably linked to the act2 promoter, wherein the promoter was modified such that restriction sites were inserted near the transcription start site.

The language of claim 1 indicates that the DNA sequence can comprise the promoter of any act2 gene. However, the specification only teaches the promoter from the *Arabidopsis* act2 gene, and does not teach that other act2 gene promoters were known in the art. The specification indicates that act2 promoters can be isolated from other sources (page 3). However, no further guidance besides this indication is provided. In the absence of further guidance, undue

experimentation would be required by one skilled in the art to practice the claimed invention with act2 promoters other than that of the *Arabidopsis* act2 gene. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). As other isolated act2 genes are not taught, their isolated promoters are not taught either.

Claim 1 also indicates that the method is for producing a genetically-modified *Compositae* plant in which the expression of the modified gene has a reduced tendency to silencing. However the specification does not teach, or even discuss, the reduction of silencing of any gene. As discussed above, the specification indicates that there was no significant loss of GUS activity in the T1 generation, compared to the assertion that there is a total inhibition of gene activity in 90% of events during transmission from one generation to the next with the 35S/GUS construct. However, it is not clear that this is a "tendency of a gene to silence." Further, no data is provided to support this assertion concerning the 35S/GUS construct. It is therefore unclear that the act2 promoter reduced the tendency of silencing of any gene. Further, the specification admits that there was variability in GUS activity levels in 3 of 12 T0 transformants (paragraph bridging pages 6-7).

The claims also encompass the production of any transgenic *Compositae* plant. However, method to transform all plant encompassed by the *Compositae* family were not known in the prior art, and not taught by the specification. The specification indicates that lettuce plants were transformed following a procedure taught in the prior art (page 6), and that sunflower explants were only transiently transformed (paragraph bridging pages 10-11). The specification

does not teach the recovery of any other stably transformed *Compositae* plants, and methods for transforming other *Compositae* plant are lacking in the prior art. In the absence of further guidance, undue experimentation would be required to use the claimed method to genetically-modify all *Compositae* species. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Further still, the claims encompass all *Compositae* plants and cells transformed with DNA construct wherein the act2 promoter is operably linked to any DNA sequence that encodes any RNA product, regardless of its function. It is not clear how one skilled in the art is to use such plants and plant cells, as their functions as unknown. See Genentech, Inc. v. Novo Nordisk, A/S, *supra*. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 16 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by An et al. (Plant J., 1996, Vol. 10, pages 107-121).

The claim is broadly drawn to any vector that comprises any DNA construct comprising a DNA sequence comprising the GUS or oxox gene under the control of any ACT2 promoter.

An et al. teaches a vector comprising the Arabidopsis ACT2 promoter operably linked to the GUS gene (page 108). The property of being useful in a process for genetically-modifying *Compositae* plants is inherent to the vector. The manner in which the vector taught by the reference is used does not change the structure of the vector itself.

6. Claims 1, 4-11, 13-15, 17, 18, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Barbour et al. (U.S. 6,670,467).

The claims are broadly drawn towards any method of producing a genetically-modified *Compositae* plant in which the expression of the modified gene has a reduced tendency to silencing, comprising transforming the plant with a heterologous DNA construct including a DNA sequence adapted to express RNA under the control of any actin2 (ACT2) gene promoter; or said method wherein the plant is lettuce or sunflower; or any genetically modified *Compositae* plant cell produced by said method; or any vector comprising said DNA construct, wherein the DNA sequence comprises the gus gene or the oxox gene; or any *Compositae* plant comprising said cells, or wherein the plants are any lettuce or sunflower, or which expresses any heterologous gene conferring herbicide resistance.

Barbour et al. teach the maize act2 gene promoter, and plants, including lettuce and sunflower, transformed with a vector comprising the maize act2 gene promoter operably linked

to genes of interest. The gene of interest can encode any product, including GUS, or that confer insect, fungicidal, or herbicide resistance, or disease resistance. The gene of interest operably linked to the act2 promoter can also be one whose product inhibits the expression of homologous or native genes, such as an antisense nucleotide sequence, that can inhibit the expression of a DNA sequence in the host plant. The gene of interest may also be expressed in the sense orientation to suppress the expression of an endogenous gene sequence (col. 4, line 1 to col. 5, line 54; col. 6, lines 23-56; col. 16, lines 9-67; col. 17, line 1 to col. 22, line 44; claims).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1 and 4-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbour et al. (U.S. Patent No. 6,670,467) in combination with Hartman et al. (WO 92/14824).

The claims are broadly drawn towards any method of producing a genetically-modified *Compositae* plant in which the expression of the modified gene has a reduced tendency to silencing, comprising transforming the plant with a heterologous DNA construct including a DNA sequence adapted to express RNA under the control of any actin2 (ACT2) gene promoter; or said method wherein the plant is lettuce or sunflower; or any genetically modified *Compositae* plant cell produced by said method; or said cell wherein the DNA construct expresses the oxox

gene; or any vector comprising said DNA construct, wherein the DNA sequence comprises the gus gene or the oxox gene; or any *Compositae* plant comprising said cells, or wherein the plants are any lettuce or sunflower, or wherein said plant expresses oxox and is resistant to sclerotinia, or which expresses any heterologous gene conferring herbicide resistance.

Barbour et al. is discussed above. Barbour et al. also teach that the gene of interest can encode disease resistant traits and can be a detoxification gene (col. 5, lines 5-10).

Barbour et al. do not teach the oxox gene.

Hartman et al. teaches methods for producing transgenic plants, including sunflower, transformed with a vector comprising the oxalate oxidase (oxox) gene, to confer resistance to sclerotinia (page 2, line 3 to page 8, line 26; page 27, line 25 to page 28, line 11; page 29, line 15 to page 32, line 22).

It would have been obvious and within the scope of one of ordinary skill in the art to modify the method of producing transformed lettuce or sunflower plants with a vector comprising the Arabidopsis ACT2 gene promoter operably linked to any gene of interest of Barbour et al., by operably linking the oxox gene of Hartman et al. to the ACT2 promoter. One would have been motivated to introduce the oxox gene into the plants, given that it confers the obvious desirable property to plants of resistance to sclerotinia, as taught by Hartman et al., and given the teaching of Barbour et al. that the gene of interest can be a gene that encodes disease resistance traits, including detoxification genes.

8. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al. (J. Exp. Bot., 1994, Vol. 45, pages 1441-1449) or Grayburn et al. (Plant Cell Rep., 1995, Vol. 14,

pages 285-289) in combination with An et al. (Plant J., 1996, Vol. 10, pages 1078-121), Hartman et al. (WO 92/14824), Bernasconi et al. (U.S. Patent No. 5,633,437), and Bidney et al. (U.S. Patent No. 6,084,164).

The claims are broadly drawn towards any method of producing a genetically-modified *Compositae* plant in which the expression of the modified gene has a reduced tendency to silencing, comprising transforming the plant with a heterologous DNA construct including a DNA sequence adapted to express RNA under the control of any actin2 (ACT2) gene promoter; or wherein said act2 gene promoter is from Arabidopsis or has substantially the sequence shown in Figure 3; or said method wherein the plant is lettuce or sunflower; or any genetically modified *Compositae* plant cell produced by said method; or said cell wherein the DNA construct expresses the oxox gene; or any vector comprising said DNA construct, wherein the DNA sequence comprises the gus gene or the oxox gene; or any *Compositae* plant comprising said cells, or wherein the plants are any lettuce or sunflower, or wherein said plant expresses oxox and is resistant to sclerotinia, or which expresses any heterologous gene conferring herbicide resistance.

Curtis et al. teach a method for transforming lettuce. The transformation vector introduced into the transgenic lettuce plants included the GUS gene (pages 1443-1448).

Curtis et al. do not teach transgenic sunflower plants, an act2 gene promoter, a herbicide tolerance gene, the oxox gene, or genes encoding RNA that inhibit the production of a homologous protein.

Grayburn et al. teach a method for transforming sunflower (pages 287-289).

An et al. teach the Arabidopsis ACT2 promoter, and transgenic plants transformed with a vector comprising theACT2 promoter operably linked to the GUS coding sequence (pages 108-113).

Hartman et al. teach methods for producing transgenic plants, including sunflower, transformed with a vector comprising the oxalate oxidase (oxox) gene, to confer resistance to sclerotinia (page 2, line 3 to page 8, line 26; page 27, line 25 to page 28, line 11; page 29, line 15 to page 32, line 22).

Bernasconi et al. teach transgenic plants with increased resistance to acetolactate synthase (ALS) inhibition by ALS herbicides, conferred by a gene encoding ALS (col. 5, line 65 to col. 6, line 12; col. 8, line 1 to col. 10, line 67; claims).

Bidney et al. teach transgenic sunflower plants expressing RNA that is antisense to the transcript of stearoyl-ACP desaturase and increase the stearate content of sunflower oil, which decreases the amount of processing to produce margarine, makes it less resistant to oxidation to make it more useful in the production of soaps an the coating of foods (col. 1, line 24 to col. 2, line 27; col. 9, line 46 to col. 12, line 53).

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to modify the method of producing transformed lettuce or sunflower plants of Curtis et al. or Grayburn et al. by replacing the promoter on the transformation vectors with any other promoter desired, including the act2 gene promoter taught by An et al. One would have been motivated to different promoters, including the act2 promoter, depending on one's desired end. It would also have been obvious to introduce any gene of interest linked to the act2 promoter, whether heterologous or homologous, depending on one's

desired end. It would have been obvious to introduce the oxox gene of Hartman et al. and the ALS gene of Bernasconi et al. One would have been motivated to introduce these genes into the plants, given the obvious desirable properties of resistance to sclerotinia and herbicides, respectively, conferred by these genes. It was also obvious that the gene of interest could have been one that inhibits the production of a homologous protein. For example, the gene of interest could have been the sequence that expresses RNA that is antisense to the transcript of stearoyl-ACP desaturase in sunflower, to increase the production of stearate, as taught by Bidney et al. One would have been motivated to express such an RNA and increase the concentration of stearate production in sunflower oil, given the advantages asserted by Bidney et al.

9. Claims 1-21 are rejected.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ashwin Mehta whose telephone number is 571-272-0803. The examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached

at 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 19, 2004

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638